

April 7, 1986

VETERINARY SERVICES MEMORANDUM NO. 800.78

Subject: Preparation and Submission of Facilities Documents

To: Biologics Licensees, Permittees, and Applicants
Director, National Veterinary Service Laboratories
Directors, VS Regions
Biologics Specialists, VS
Area Veterinarian in Charge, VS

I. PURPOSE

The purpose of this memorandum is to provide a checklist to be used in preparing and submitting facilities documents specified in Title 9, Code of Federal Regulations, Part 108. References to the regulations are included. A suggested blueprint legend page format is also included as an addendum.

II. PREPARATION

A. Plot plans

1. All buildings on the land area of the licensed premises must be shown on the drawing.

Reference: Section 108.3

2. Entire premises must be drawn to a standard scale on one sheet of paper.

Reference: Section 108.3(a)

3. Boundaries of premises must be identified on the drawing.

Reference: Section 108.3(b)

4. Drawings must show, in proper scale, distance relationship of buildings with each other.

Reference: Section 108.3(c)

5. Buildings must be identified by unique letter or number on the drawing.

Reference: Section 108.3(d)

6. The use of adjacent properties must be shown on the drawing.

Reference: Section 108.3(e)

7. Compass points must be shown on the drawing.

Reference: Section 108.3(f)

8. The date of preparation must be shown.

Reference: Section 108.3(g)

9. The signature of the responsible official of the firm must be applied.

Reference: Section 108.3(h)

B. Blueprints

1. Plans must be drawn to scale on blueprint or white paper.

Reference: Section 108.4(a)

2. Areas used for preparing biological products must be illustrated in detail for each floor.

Reference: Section 108.4(b)

3. If only a portion of a floor is used for preparation of biological products, functions and activities on the remainder of the floor must be shown.

Reference: Section 108.4(c)

4. For multistory buildings, activities on each floor must be indicated.

Reference: Section 108.4(d)

5. Each room must be identified by unique number or letter.

Reference: Section 108.4(e)

6. Location of stationary equipment used in preparing biological products should be shown and identified by a code number or letter.

Reference: Section 108.4(f)

7. Show the location of windows and doors. Water outlets, drains, and lighting may be described on blueprints or in legend descriptions.

Reference: Section 108.4(g)

8. Compass points must be shown.

Reference: Section 108.4(h)

9. The number or letter used to identify the building on the plot plan must be shown.

Reference: Section 108.4(i)

10. The date of preparation must be shown.

Reference: Section 108.4(j)

11. The signature of the responsible official of the firm must be applied.

Reference: Section 108.4(k)

C. Legends

1. Plot plan legends

a. Each plot plan legend must identify the corresponding plot plan. Pages must be numbered.

Reference: Section 108.5

b. The functions performed in each building must be stated.

Reference: Section 108.5(a)(1)

c. A brief, nontechnical description of construction materials must be included.

Reference: Section 108.5(a)(2)

2. Blueprint legends

a. Each blueprint legend must identify the corresponding building or floor. Pages must be numbered.

Reference: Section 108.5

b. Each room must be listed, along with fractions prepared and functions performed in each. For rooms where product is exposed, a description of decontamination procedures must be added.

Reference: Section 108.5(b)(1)

c. The room description must include identity of coded stationary equipment.

Reference: Section 108.5(b)(2)

d. The room description must include identity of other movable equipment essential to functions performed in the room.

Reference: Section 108.5(b)(3)

III. SUBMISSION AND FILING

A. Initial submissions should be made to the Senior Staff Veterinarian, Veterinary Biologics Staff, VS, APHIS, USDA, 6505 Belcrest Road, Hyattsville, MD 20782, for preliminary review.

B. Subsequent submissions should be made to the Veterinarian in Charge, Veterinary Biologics Field Office, 515 Grand Avenue, Ames, IA 50010.

C. Acceptable submissions will be stamped as filed. One stamped copy will be returned to the submitter and one copy filed at the Veterinary Biologics Field Office.

Reference: Section 108.7

/s/

J. K. Atwell
Deputy Administrator
Veterinary Services
Enclosure (Not included)
Addendum (Not included)